REMARKS/ARGUMENTS

Applicant has received and carefully reviewed the Final Office Action mailed August 24, 2009. Currently, claims 1-4, 16-29, and 31-41 are pending, with claims 11, 12, and 14 previously withdrawn from consideration. Claims 1-10, 13, 16-29, and 31-41 have been rejected. Applicant respectfully traverses all adverse assertions and rejections presented in the Office Action. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 1-10, 13, 16-29, and 31-41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Huebsch et al. (U.S. Patent No. 6,312,446) in view of Redmond et al. (U.S. Patent No. 6,334,865) and Lafontaine et al. (U.S. Patent No. 5,964,782). After careful review, Applicant must respectfully traverse the rejection.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03).

The Office Action acknowledges that Huebsch et al. do not disclose the collapse actuator assuming a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator in order to permit the detachable distal end to pass proximally through the distal aperture, as required by independent claims 1, 26, and 33. Instead, Huebsch et al. appear to teach actuator 230 may be detached from closure device 200 by rotating distal end 232 of actuator 230 to align with distal opening 234 in closure device 200 and then pulling the actuator proximally through the device. Huebsch et al. do not appear to teach or suggest deforming the actuator to facilitate removal.

The Office Action has proposed to modify actuator 232 of Huebsch et al. in accordance with the teachings of Redmond et al. to provide a deformable distal end to facilitate and simplify retraction of the actuator without the need for rotation. Applicant believes that the proposed combination and modification is improper.

"The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)." (MPEP 2142).

Nowhere do Huebsch et al. appear to suggest modifying actuator distal end 232 to be deformable to facilitate detachment. Similarly, nowhere do Redmond et al. appear to suggest that distal end 24 of barrier actuator 22 is deformable to facilitate detachment or that one would be motivated to make actuator end 232 of Huebsch et al. deformable to facilitate detachment. The Office Action appears to imply that since Redmond et al. disclose barrier actuator 22 to be a "flexible, wire-like" component (column 5, line 65), that it has a deformable distal end that may be detached from barrier assembly 4. Applicant respectfully disagrees.

Redmond et al. expressly disclose "[b]arrier assembly 4 includes…[t]he distal end 24 of barrier actuator 22 is secured to the center of semipermeable barrier 26" (column 5, lines 64-67). Nowhere do Redmond et al. appear to consider detaching actuator 22 from barrier assembly 4. In fact, Redmond et al. appear to require actuator 22 to remain attached to barrier assembly 4 in order to be able to remove barrier assembly 4 from the vessel. Therefore, Redmond et al. do not appear to suggest that the distal end may be deformable in order to facilitate detachment.

Accordingly, Applicant submits that the cited references do not support the asserted reasoning and that the asserted reasoning is instead a conclusory statement that cannot support a conclusion of obviousness.

"If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)". (MPEP 2143.01 V).

Applicant further submits that modification of actuator end 232 of Huebsch et al. to permit it to deform such that the deformed end may be pulled through opening 234 without rotation, as proposed in the Office Action, may render the device unsuitable for its intended use. Applicant submits that in order to perform the required proximal

collapse of closure device 200, a certain amount of force must be applied. In order to deform end 232 after collapse of the device, additional force will be required. Applicant submits that this additional force may render the device unsuitable for its intended use, as it will subject the affected tissue to additional pulling forces and stresses, which could promote undesirable bleeding or tissue damage.

For at least the reasons discussed above, the combination of Redmond et al. with Huebsch et al. appears to be improper, and thus incapable of supporting the asserted obviousness rejection.

The Office Action also acknowledges that Huebsch et al. do not disclose "the collapsible backing made of pile or fabric, wherein the pile engaging hooks engage portions of the pile backing to retain the pile backing in the collapsed position"; "bioabsorbable materials"; or "[t]he collapse actuator having a frangible connection to the distal end of the closure component".

Lafontaine et al. is introduced in an effort to supply the bioabsorbable backing with tissue or adventitia engaging hooks that entangle in the backing located proximal of the hooks as the backing moves from the non-collapsed position to the collapsed position to retain the backing in a collapsed configuration, citing Figs. 34A-34C.

Even if the exterior of the struts of Huebsch et al. were to be covered with the bioabsorbable backing of Lafontaine et al., the hooks thereon would not appear to be capable of engaging with the backing when the struts are in their collapsed configuration. Hooks disposed along the proximal portions of the distal struts (struts distal of central portion 218) and along the distal portions of the proximal struts (struts proximal of central portion 218) would appear to be prevented from contacting the pile of the opposing strut for the reason that they are separated by the intervening tissue and spaced apart by the central portion (218) of the device. Similarly, hooks disposed on the proximal portion of the proximal struts and the distal portion of the distal struts appear to face away from any other portion of the device that may have the proposed pile, and thus the hooks cannot engage the pile. Therefore, Huebsch et al. in view of Lafontaine et al. appear to be incapable of combination to achieve the necessary configuration of hooks which may engage pile as required by the claims.

Furthermore, the proposed addition of the pile of Lafontaine et al. to the closure device of Huebsch et al. appears to be unnecessary in view of the locking elements already in place on the Huebsch et al. closure device.

Lastly, the Office Action asserts that Lafontaine et al. disclose a "frangible, mechanically releasable connection", citing column 20, lines 14-19. Applicant respectfully disagrees. Lafontaine et al. appear to disclose a pair of concentric gripping or clamping cylinders (386, 388) that pinch a proximal portion of closure ring 344. In order to release closure ring 344, the outer cylinder is withdrawn, which removes the clamping force holding the ring in place. Inner cylinder 388 is then manipulated to release the ring from gripping section 394. There does not appear to be any fixed connection to be broken (ring 344 does not appear to be bonded, integrally formed, or otherwise fixedly attached to gripping section 394 of inner cylinder 388), as the term frangible would indicate. As such, none of the cited references appear to disclose a frangible connection between the actuator and the closure component.

For at least the reasons discussed above, Huebsch et al. in view of Lafontaine et al. and Redmond et al. do not appear to properly combine to teach or suggest all of the claim limitations of independent claims 1, 26, and 33, as is required to establish a *prima facie* case of obviousness. Therefore Applicant believes claims 1, 26 and 33 are indeed patentable over the cited references. Since claims 2-10, 13, 16-25, 27-29, 31, 32, and 34-41 depend from claims 1, 26, or 33 and add additional elements thereto, Applicant believes that these claims are also patentable over the cited references. Applicant respectfully requests that the rejection be withdrawn.

Conclusion

In view of the foregoing, all pending claims are believed to be in condition for allowance. Further examination and withdrawal of the rejections are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,

Date: Oct. 19, 2009

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